

The examiner has required restriction to one of the following inventions:

Group I, including claims 1-5, 10-26 and 31-39, drawn to a method of preventing or inhibiting neuronal degeneration by administering activated T cells which have been activated by Cop 1 or a Cop 1-related protein;

Group II, including claims 1, 6-22, 27-30 and 31-39, drawn to a method of preventing or inhibiting neuronal degeneration by administering to an individual Cop 1 or a Cop 1-related protein;

Group III, including claims 1-5 and 10-18, drawn to a method for promoting nerve regeneration by administering activated T cells which have been activated by Cop 1 or a Cop 1-related protein; and

Group IV, including claims 1, 6-9 and 10-18, drawn to a method for promoting nerve regeneration by administering Cop 1 or a Cop 1-related protein.

This restriction requirement is respectfully traversed.

First of all, in order to be responsive, applicants hereby elect the claims of Group II, drawn to a method for preventing or inhibiting neuronal degeneration by administering an effective amount of Cop 1 or a Cop 1-related peptide or polypeptide.

The restriction between Groups I and II is traversed because the dichotomy between *in vivo* and *in vitro* activation of the T cells is not a true dichotomy between patentably distinct inventions. In order to better emphasize this point, new claim 40 has now been added, which is a true generic claim, directed to reducing neuronal degeneration by "causing cells which have been activated by Cop 1 or a Cop 1-related peptide or polypeptide to accumulate at the site of neuronal degeneration". It does not matter whether this accumulation is caused by active administration of the Cop 1 that causes the activated T cells to be generated *in vivo*, or by passive administration of activated T cells directly, which T cells may have been activated *in vitro*. Accordingly, this linking claim 40 requires that the examiner examine all of the species of administration that cause the Cop 1 activated T cells to accumulate at the site of neuronal degeneration and thereby inhibit any neuronal degeneration, regardless of whether the T cells are activated *in vitro* or *in vivo*.

The language for new claim 40 is supported by the present specification. That the purpose of the administration of Cop 1 is to cause the accumulation of Cop 1 activated T cells at the site of neuronal degeneration is supported by the paragraph bridging pages 32 and 33 of the present specification, where it states:

[T]he Cop or Cop 1-related peptide or polypeptide antigen or derivative thereof activates T cells *in vivo* to produce a population of T cells that accumulates at a site of injury or disease of the CNS or PNS.

That the passive administration of the T cells themselves are administered for the same purpose is evident from the second full paragraph on page 48, where it states:

T cells activated with Cop 1 will accumulate at the site of neural degeneration and facilitate inhibition of this degeneration.

See also the second paragraph on page 49, which reads:

Similarly, if the active principle is activated T cells, then the particular formulation and mode of administration should be tested to ensure that the active T cells being administered reach the bloodstream in an active state so that they can home to the site of injury in the CNS in accordance with the present invention.

The required procedure when a linking claim, such as claim 40, is present is set forth at MPEP §809.03. As claim 40 serves as an linking claim, reconsideration and withdrawal of the restriction requirement as between Groups I and II and action on all the claims now present in the case are respectfully urged.

As to the allegedly patentably distinct dichotomy between the promotion of nerve regeneration and the prevention or inhibiting of neuronal degeneration, i.e., Groups I and II on the one hand and Groups III and IV on the other hand, this

part of the restriction requirement should also be withdrawn. The examiner states that they are different methods because they require different ingredients, process steps and end points, wherein each is not required one for another. It is urged, however, that the difference lies only in the preamble of claim 1 and that the ingredients, process steps and end points are substantially the same. Usually, if nerve regeneration is promoted by the present invention, then neuronal degeneration will simultaneously be prevented or inhibited and vice versa. Thus, a reference directed to one will inherently anticipate the other.

The field of search is irrelevant to the determination of whether two claims are directed to independent and distinct inventions. The only issue is whether the claims are patentable over one another. The search criteria is only applicable as a secondary criteria which is required after it is determined that two claims are independent and distinct. See MPEP §803. As a claim to a method for preventing or inhibiting neuronal degeneration would not be patentably distinct from a claim for promoting nerve regeneration wherein the process steps are otherwise identical, these processes are not independent or distinct. Reconsideration and withdrawal of this part of the restriction requirement is also respectfully urged.

As to Groups III and IV, they should be examined together for the same reasons as discussed above with respect to Groups I and II.

Claim 1 is a generic claim and as all of the features of claim 1 possess unity of invention, i.e., they all rely on the activity *in vivo* of Cop 1 activated T cells, it would be inappropriate to require that these claims be amended to eliminate non-elected inventions. See MPEP §803.02. Thus, the restriction requirement should at least be modified so as to be an election requirement.

For all of these reasons, reconsideration and withdrawal of the restriction requirement and examination of all the claims now present in the case are respectfully urged.

Besides the restriction requirement, the examiner has made a series of election requirements. For each of the election requirements, however, it is understood that if a generic claim is finally found to be allowable, all of the disclosed species will be examined. Accordingly, no traversal of these species requirements is made at the present time. Applicants hereby elect (a) central nervous system, (c) Cop 1, (e) injury, (g) spinal cord injury, and (w) alanine, glutamic acid, lysine and tyrosine.

Accordingly, reconsideration and withdrawal of the restriction requirement and examination of the elected species

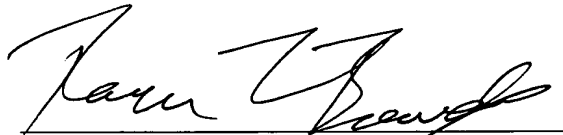
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and, following examination and allowance of the elected species, examination and allowance of all the species, are earnestly solicited.

Respectfully submitted,

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